Howard Ross Cabot, Bar No. 006669
Christopher S. Coleman, Bar No. 018287
PERKINS COIE BROWN & BAIN P.A.
2901 North Central Avenue, Suite 2000
Post Office Box 400
Phoenix, Arizona 85001-0400
Telephone: 602.351.8000
Facsimile: 602.648.7000
HCabot@perkinscoie.com
CColeman@perkinscoie.com

Attorneys for Defendants

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

Edward Finck, a single man,

Plaintiff,

v.

Pfizer, Inc., a Delaware corporation with its principal place of business in New York; Pharmacia Corporation, a Delaware corporation with its principal place of business in New Jersey; Monsanto Co., a subsidiary of Pharmacia and a Delaware corporation with its principal place of business in Missouri; G.D. Searle & Company, a Delaware corporation with its principal place of business in Illinois,

Defendants.

No. CV 06-3017-PHX-JAT

ANSWER

(Jury Trial Requested)

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME Defendants Pfizer Inc. (incorrectly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a "Monsanto

Company"[1]) ("Pharmacia"), and G.D. Searle LLC (improperly captioned in Plaintiff's Complaint as "G.D. Searle & Company") ("Searle"), collectively "Defendants," and file this their Original Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex®. Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

II.

ORIGINAL ANSWER

Response to Introduction

Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers

[1] Plaintiff's Complaint names "Monsanto Company" as a defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex®. Given that Plaintiff alleges in his Complaint that Monsanto Company was involved in developing Celebrex®, *see* PLAINTIFF'S COMPLAINT at ¶ 4, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is and was safe and effective when used in accordance with its FDA-approved prescribing information. As for the allegations in this paragraph of the Complaint regarding the NCI study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny that Celebrex® is defective and deny the remaining allegations in the first unnumbered paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

1. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations concerning the Plaintiff's citizenship, and therefore deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations contained in this paragraph of the Complaint.

3. Defendants admit that Pharmacia is a Delaware corporation with its principal pace of business in the State of New Jersey, and that Pharmacia does business in Arizona. Defendants admit that, during certain periods of time, Pharmacia marketed and

co-promoted Celebrex® throughout the United States to be prescribed by healthcare providers who are authorized by law to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations contained in this paragraph of the Complaint.

4. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold, resold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations contained in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by reference in each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

5. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, during certain periods of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States, including Arizona, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that as a result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants deny the remaining allegations contained in this paragraph of the Complaint.

6. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Pfizer Defendants also admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States, including Arizona, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations contained in Paragraph 6 of the Complaint.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the amount in controversy, and therefore deny the same. However, Defendants admit that Plaintiff claims that the amount in controversy exceeds $75,000, exclusive of interests and costs. Defendants are without knowledge or information sufficient to form a belief as to the judicial district in which the asserted claims allegedly arose and therefore denies that venue is proper in this district pursuant to 28 U.S.C. § 1391. Defendants further deny committing a tort within the State of Arizona and deny the remaining allegations in this paragraph of the Complaint.

Response to General Allegations

8. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective

when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

9. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Plaintiff's allegations regarding "successor in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

11. Defendants admit that Pfizer, Pharmacia, and Searle are registered to do business in Arizona. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

13. This paragraph of the Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex® and whether Plaintiff suffered a myocardial infarction on January 18, 2002, and therefore deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

15. Defendants admit that Celebrex® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). The remaining allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the remaining allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

16. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

17. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

18. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is

deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

23. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants deny the allegations in this paragraph of the Complaint.

25. Defendants deny the allegations in this paragraph of the Complaint.

26. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27. As for the allegations in this paragraph of the Complaint regarding the CLASS study, Defendants state that the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the

study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that referenced the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

30. Defendants admit that the CLASS study results were provided to the FDA ADA Committee and deny the remaining allegations in this paragraph of the Complaint.

31. As for the allegations in this paragraph of the Complaint regarding the CLASS study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. As for the allegations in this complaint regarding the findings of the FDA Arthritis Drugs Advisory Committee, Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. As for the allegations in this paragraph of the Complaint regarding the CLASS study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. As for the allegations in this complaint regarding the findings of the FDA Arthritis Drugs Advisory Committee, Defendants state that the transcripts of the

FDA Arthritis Drugs Advisory Committee hearings speaks for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

34. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

35. Defendants admit that Searle submitted a New Drug Application ("NDA") for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA

granted approval of the NDA for Celebrex® submitted by Searle on June 29, 1998. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Defendants admit that Searle submitted an NDA for Celebrex® on June 29, 1998. Defendants admit that on December 31, 1998, the FDA approved Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that Celebrex® was released for sale in the United States in February 1999. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants deny the allegations in this paragraph of the Complaint.

39. As for the allegations in this paragraph of the Complaint regarding the CLASS study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. As for the allegations in this Paragraph of the Complaint regarding an article published in the September 13, 2000 issue of JAMA, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants admit that, before approving a drug, the FDA must conclude that a drug is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. As for the allegations in this paragraph of the Complaint regarding the CLASS study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. As for the allegations in this Paragraph of the Complaint regarding the JAMA article, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding "data on the FDA's website." Defendants lack sufficient information or knowledge to form a belief as to the truth of such allegations and therefore deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced submission speaks for itself and respectfully refer the Court to the submission for its actual language and text. Any attempt to characterize the submission is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

43. As for the allegations in this Paragraph of the Complaint regarding the Medical Officer's Review, Defendants state that the Medical Officer's Review speaks for itself and respectfully refer the Court to the Medical Officer's Review for its actual language and text. Any attempt to characterize the Medical Officer's Review is denied. As for the allegations in this Paragraph of the Complaint regarding the "JAMA article",

Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. As for the allegations in this paragraph of the Complaint regarding the CLASS study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. As for the allegations in this Paragraph of the Complaint regarding the "article published in JAMA", Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. As for the allegations in this Paragraph of the Complaint regarding the Medical Officer's Review, Defendants state that the Medical Officer's Review speaks for itself and respectfully refer the Court to the Medical Officer's Review for its actual language and text. Any attempt to characterize the Medical Officer's Review is denied. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding "the FDA's files." Defendants lack sufficient information or knowledge to form a belief as to the truth of such allegations and therefore deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize

the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

47. Defendants admit that the FDA Division of Drug Marketing, Advertising and Communications sent Searle a letter dated July 16, 1997. Defendants respectfully refer the Court to the letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants respectfully refer the Court to the letters for their actual language and full text. Any attempt to characterize the letters is denied. Defendants admit that the FDA sent letters to Searle dated October 6, 1999, April 6, 2000 and November 14, 2000. Defendants respectfully refer the Court to the letters for their actual language and full text. Any attempt to characterize the letters is denied. Defendants admit that the FDA sent a letter to Pharmacia dated February 1, 2001, and that the FDA sent a letter to Pfizer dated January 10, 2005. Defendants respectfully refer the Court to the letters for their actual language and full text. Any attempt to characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants state that the referenced letter speaks for itself, and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the

FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants deny the allegations in this paragraph of the Complaint.

51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that as indicated in the package insert approved by the FDA, Celebrex® has been approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile

rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

52. To the extent that the allegations in this paragraph of the Complaint are not directed at Defendants, no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for such allegations. Defendants lack sufficient information or knowledge to form a belief as to the truth of such allegations and therefore deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. The allegations in this paragraph of the Complaint regarding "other drug companies" are not directed at Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding "other drug companies." Defendants lack sufficient information or knowledge to form a belief as to the truth of such allegations and therefore deny the same. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding "blockbuster drugs." Defendants lack sufficient information or knowledge to form a belief as to the truth of such allegations and therefore deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe

drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

56. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

57. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

58. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

60. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

61. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

62. Defendants state that the referenced FDA documents speak for themselves and respectfully refer the Court to the documents for their actual language and text. Any attempt to characterize the documents is denied. Defendants deny the remaining allegations this paragraph of the Complaint.

63. Defendants admit that the FDA sent a letter to Searle dated October 6, 1999. Defendants respectfully refer the Court to the letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

64. Defendants admit that the FDA sent a letter to Searle dated April 6, 2000. Defendants respectfully refer the Court to the letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants admit that the FDA sent a letter to Searle dated November 14, 2000. Defendants respectfully refer the Court to the letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

66. Defendants admit that the FDA sent a letter to Pharmacia dated February 1, 2001. Defendants respectfully refer the Court to the letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to referenced letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the

potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to referenced letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

69. As for the allegations in this paragraph of the Complaint regarding advertising and packaging materials, Defendants state that the referenced advertising and packaging materials speaks for themselves and respectfully refer the Court to the advertising and packaging materials for their actual language and text. Any attempt to characterize the advertising and packaging materials is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that the referenced advertising and packaging materials speak for themselves and respectfully refer the Court to the advertising and packaging materials for their actual language and text. Any attempt to characterize the advertising

and packaging materials is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that the referenced advertising and packaging materials speaks for themselves and respectfully refer the Court to the advertising and packaging materials for their actual language and text. Any attempt to characterize the advertising and packaging materials is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. As for the allegations in this paragraph of the Complaint regarding advertising and packaging materials, Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that the referenced print advertisements speak for themselves and respectfully refer the Court to the print advertisements for their actual language and text. Any attempt to characterize the print advertisements is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that the referenced print advertisements speak for themselves and respectfully refer the Court to the print advertisements for their actual language and text. Any attempt to characterize the print advertisements is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that the referenced print advertisement speaks for itself and respectfully refer the Court to the print advertisement for its actual language and text. Any attempt to characterize the print advertisement is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Strict Liability – Failure to Warn

75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Negligence

79. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

80. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Implied Warranty

84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

85. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

86. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

88. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Express Warranty

89. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

90. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved

prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

91. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Deceit by Concealment

93. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

94. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

96. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

97. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Negligent Misrepresentation

98. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

99. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

100. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Punitive Damage Allegations
(As to only the First, Second, Fifth, and Sixth Causes of Action)

105. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

107. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex®

is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

108. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 109 of the Complaint, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

III.
GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate her damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to the Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical

product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff are barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Arizona, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Arizona law.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Arizona. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v.*

Gore, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Plaintiff's claims are barred in whole or in part by the affirmative defenses referenced in A.R.S. § 12-683.

Fifty-sixth Defense

56. Defendants reserve the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

V.
JURY DEMAND

Defendants hereby demand a trial by jury.

VI.
PRAYER

WHEREFORE, Defendants prays that Plaintiff take nothing by his suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which they may be justly entitled.

Dated: June 5, 2007

PERKINS COIE BROWN & BAIN P.A.

By s/ Christopher S. Coleman
Howard Ross Cabot
Christopher S. Coleman
2901 North Central Avenue, Suite 2000
Post Office Box 400
Phoenix, Arizona 85001-0400

Attorneys for Defendants

CERTIFICATE OF SERVICE

☒ I hereby certify that on June 5, 2007, I electronically transmitted the attached documents to the Clerk's Office using the ECF System for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

Stanley J. Marks, Esq.
smarks@begamlaw.com
Serena C. Montague, Esq.
smontague@begamlaw.com
BEGAM, LEWIS & MARKS, P.A.
111 West Monroe Street, Suite 1400
Phoenix, Arizona 85003-1787
Attorneys for Plaintiff

s/ Janet Roe

LEGAL13298468.1